IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS WACO DIVISION

ZANOPRIMA LIFESCIENCES, LTD,	§	
Plaintiff,	§ § §	
V.	§ 8	Civil Action No. 22-268
HANGSEN INTERNATIONAL GROUP	§	
LTD,	§	
	§	
Defendant.	§	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Zanoprima Lifesciences, Ltd. ("Zanoprima" or "Plaintiff"), by and through its undersigned counsel, pleads the following against Defendant Hangsen International Group Ltd. ("Hangsen" or "Defendant"), and alleges as follows:

THE PARTIES

- 1. Plaintiff Zanoprima is a corporation duly organized and existing under the laws of the United Kingdom. Zanoprima's principal place of business is 5th Floor, Charles House, 108-110 Finchley Road, London NW3 5JJ, Great Britain.
- 2. On information and belief, Hangsen is a corporation duly organized and existing under the laws of China. Further, on information and belief, Hangsen maintains a regular and established place of business in Shenzhen, Guangdong, China and/or TsimSha Tsui, Kowloon, Hong Kong.

BACKGROUND, JURISDICTION, AND VENUE

3. This is an action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq. Accordingly, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

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A. Zanoprima

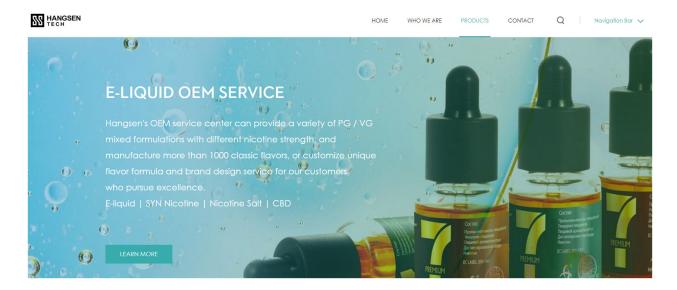
- 4. Zanoprima was founded in June 2014 by Ashok Narasimhan and Nicholas Hyde with the aim of reducing tobacco-related harm by designing and developing replacement products. Sadly, Nicholas Hyde passed away in September 2020 following a battle with lung cancer.
- 5. The vision for Zanoprima arose from a concern in the pharmaceutical industry regarding the provenance and purity of tobacco-derived nicotine being used in the very products intended to reduce addiction to tobacco as well as disease and death associated with tobacco. In response to this concern, Zanoprima sought to develop a process of nicotine synthesis that would create nicotine chemically identical to that derived from the tobacco plant but (a) was devoid of tobacco specific nitrosamines, carcinogens, tobacco alkaloids, and other impurities, (b) was traceable with high levels of enantiomeric and chemical purity, and (c) could rival the pricing of tobacco-derived nicotine. Unfortunately, at that time, there was no economically-viable method to synthesize and bulk-produce (S)-nicotine, the predominant and more active enantiomer of nicotine found in the tobacco plant.
- 6. In November 2014, Zanoprima's researchers began research and development of a synthesis approach that involved an intermediate compound that had been largely overlooked in nicotine research, (S)-nornicotine. Zanoprima's researchers ultimately envisioned a process whereby biocatalysis, using an enzyme, could produce an enantiomerically pure (S)-nornicotine, which could then be methylated to produce the desired enantiomerically pure (S)-nicotine. However, transitioning this concept to reality required a significant investment in time and resources. Zanoprima worked tirelessly to screen and identify which enzymes to use, to improve the enzyme reaction, and to optimize the methylation of (S)-nornicotine.
- 7. After nearly four years of extensive research and substantial investment, by November 2018, Zanoprima had developed a novel and reliable method to synthesize (S)-nicotine

and promptly filed that patent application on the method that would ultimately issue as U.S. Patent No. 10,913,962 (the "'962 Patent").

8. Zanoprima manufactures synthetic (S)-nicotine using its patented method in an FDA-approved manufacturing facility.¹ Zanoprima markets and sells its synthetic (S)-nicotine, including in the United States, with the goal of facilitating the movement towards a tobacco-free world.²

B. Hangsen

9. Hangsen is a manufacturer and distributor of e-cigarettes, e-liquid, nicotine salt, and synthetic nicotine.³



10. Hangsen directly competes with Zanoprima in the marketplace. For example, Hangsen imports and sells synthetic (S)-nicotine and products that include synthetic (S)-nicotine (the "Accused Products") in the United States. The Accused Products directly compete with Zanoprima's patented synthetic (S)-nicotine products.

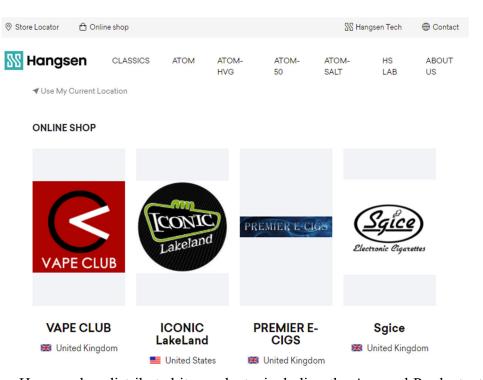
¹ https://www.zanoprima.com/our-products

² https://www.zanoprima.com/

³ https://www.hkhangsen.com/list/index/cid/7.html

- 11. Hangsen infringes the '962 Patent by selling, offering for sale, using, making, and/or importing the Accused Products into the United States.
- 12. Hangsen is subject to this Court's personal jurisdiction because Hangsen has sufficient minimum contacts within Texas pursuant to due process and the Texas Long Arm Statute, Tex. Civ. Prac. & Rem. Code § 17.042.
- 13. Hangsen has purposefully directed its products, including the Accused Products, and activities at the United States, including Texas, and has engaged in conduct that indicates an intent or purpose to serve the market in the United States and Texas, such as designing its products broadly for the United States market, advertising in the United States, and marketing and selling its products through one or more distributors in the United States and Texas.
- 14. Hangsen has sold or distributed products to multiple U.S. distributors, who sell their products throughout the United States, including in Texas. On information and belief, Hangsen has sold the Accused Products to Triton Distribution Group, a distributor located in Richardson, Texas. Furthermore, on information and belief, Hangsen directs online shoppers to purchase Hangsen products from U.S. distributors, which can be purchased from those U.S. distributors and shipped throughout the United States, including Texas.⁴

⁴ https://www.hangsen.com/online-shop



- 15. Hangsen has distributed its products, including the Accused Products, to retailers and manufacturers throughout the United States, including Texas. For example, upon information and belief, Vapetasia, who has a principal place of business is Richardson, Texas, is a manufacturer of final consumer products, including Vapetasia Salts E-Liquid, that incorporate the Accused Products. Vapetasia Salts E-Liquid is available for sale within the state of Texas. On March 8, 2022, four packages of Vapetasia Salts E-Liquid were purchased at Austin Pineapple Express, a retailer at 3401 Guadalupe Street in Austin, Texas 78705. A true and correct copy of a picture of the receipt and the four packages is attached as Exhibit 1 and incorporated herein.
- 16. Additionally, as another example, on September 10, 2020, when Hangsen "announced the global release of SYN Nicotine," Hangsen also stated that "SYN Nicotine e-liquids will be used in Geek Bar's product, which is set to launch soon in the North America

market."⁵ Indeed, Geek Bar currently advertises on its "Synthetic Nicotine Disposables" webpage that "[t]he inaugural batch of custom-made SYN Nicotine e-liquids will be used in Geek Bar products. And in the foreseeable future we will continue to use tobacco-free nicotine in all our existing and up-coming products"⁶ On information and belief, Geek Bar products are sold in Texas through Texas distributors and include the Accused Products.

17. On information and belief, Hangsen also provides, sells, and/or offers to sell Accused Products to Genmist, a company that sells nicotine pouches throughout the world, including the United States. Genmist advertises on its website that Genmist nicotine pouches utilize "[t]he patented synthetic nicotine Motivo [that] has already been used on nicotine pouches and HNB products sold to worldwide."⁷



Genmist nicotine pouches are packed 20 pouches into one plastic can. Genmist currently has 5 flavours and comes in both 9 and 14mg strengths. Genmist Synthetic Nicotine is a patented nicotine ingredient that is not derived from tobacco, thus it carries none of those toxic ingredients, yet deliver the same hit and satisfaction for users' nicotine needs. As a relatively new product, users may not be aware of its potential and usage. It is safer and more stable than the tobacco derived nicotine in the market.

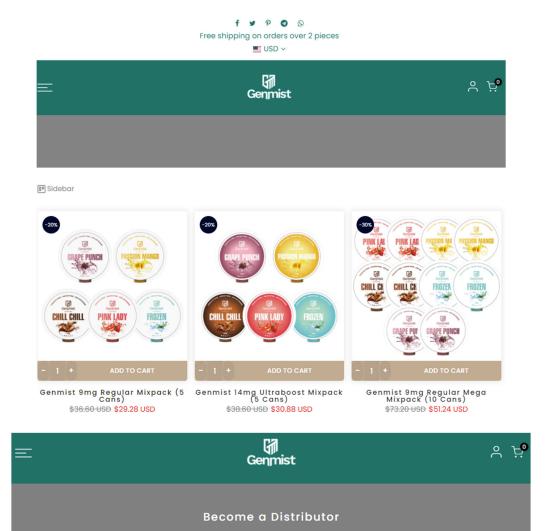
18. On information and belief, Genmist has physical locations within the United States and makes, sells, or offers to sell its nicotine pouches that include the Accused Products to customers within the United States, including Texas:⁸

⁵ https://apnews.com/press-release/pr-newswire/corporate-news-products-and-services-tobacco-products-manufacturing-technology-consumer-products-and-services-625259e1af8f52e68920659dbfa60f58

⁶ http://www.geekbar.com/article/detail.html?id=8

⁷ https://www.genmist.shop/blogs/genmist-blog/top-nicotine-pouch-brands

⁸ https://www.genmist.shop/collections/nicotine-pouches; https://www.genmist.shop/pages/distributorship



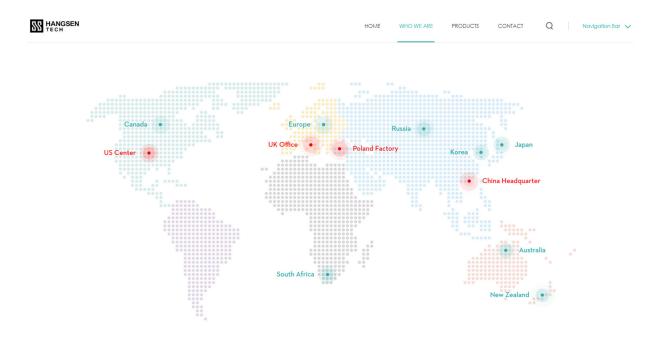
Genmist products are sold in USA, Europe, Japan, China and South East Asia. Genmist has received TPD approvals for more than 10 countries in Europe.

Our distributor network is a key element for Genmist's global success. We work with our local distributors to achieve common goal: build a tobacco free world with Genmist. We provide local local distributors with various supports.

If you are interested in becoming our distributor, please contact us at sales@genmist.com.

19. Upon information and belief, Hangsen both operates a U.S.-based center that engages in the importation of Hangsen products into the United States as well as the distribution and/or sale of Hangsen products throughout the United States, including Texas, and actively

promotes itself and makes public its purposeful availment of the United States', including Texas' market.⁹



20. Venue is proper in this judicial District pursuant to at least 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b), as well as under the "alien venue rule." *Brunette Machine Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706 (1972); *In re HTC Corp.*, 889 F.3d 1349 (Fed. Cir. 2018). As noted above, Hangsen is a foreign entity that is subject to personal jurisdiction in this Court.

THE ASSERTED PATENT AND THE ACCUSED PRODUCTS

C. The Asserted Patent

- 21. On February 9, 2021, the '962 Patent, entitled "Process of Making (S)-Nicotine," was duly and legally issued by the United States Patent and Trademark Office. A true and correct copy of the '962 Patent is attached as Exhibit 2 and incorporated herein.
- 22. The '962 Patent names Raymond McCague and Ashok Srinivasan Narasimhan as co-inventors.

⁹ https://www.hkhangsen.com/list/index/cid/3.html

- 23. The '962 Patent claims priority to European Patent Office Application No. 18206826, which has a filing date of November 16, 2018.
- 24. The '962 Patent has been in full force and effect since its issuance. Zanoprima is the owner, by assignment, of all rights, title, and interest in and to the '962 Patent, including the right to seek damages for past, current, and future infringement thereof.
- 25. The '962 Patent states that it "relates to a process for synthetically producing (S)-nicotine ([(S)-3-(1-methylpyrrolidin-2-yl) pyridine])." Ex. 2 at 1:5–7.
- 26. Claim 1 of the '962 Patent recites: "A process of making (S)-nicotine comprising the steps of: (i) reducing myosmine with an enzyme with imine reductase activity to form (S)-nornicotine; and (ii) methylating the (S)-nornicotine formed from step (i) to form (S)-nicotine; wherein step (ii) is carried out by way of reductive methylations; and wherein in step (ii) the (S)-nornicotine is reductively methylated, using formaldehyde or a formaldehyde-based compound in the presence of a reductant." Ex. 2 at 19:59–20:59. The '962 Patent discloses the following reaction scheme:

Ex. 2 at 7:41-59.

D. The Accused Products

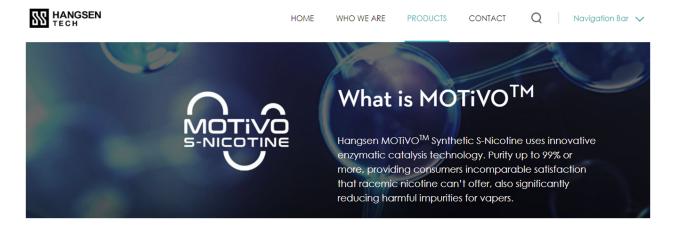
27. Hangsen's Accused Products that infringe the '962 Patent include Hangsen's alleged high-purity synthetic (S)-nicotine and nicotine products that are marketed and sold under various names including as MOTiVO Synthetic S-Nicotine ("MOTiVO"). For example, one United States retailer has advertised its "Island Breeze" product as containing "Motivo S-Nicotine" using Hangen's MOTiVO logo and referring to the product's "Tobacco Free Nicotine:"



https://www.ecigcharleston.com/Island-Breeze-Synthetic-60ml-p/islandbreezesyn60.htm.

28. According to Hangsen's website, Hangsen's "MOTiVO Synthetic S-Nicotine uses innovative enzymatic catalysis technology" with "[p]urity up to 99% or more," which "provid[es] consumers incomparable satisfaction that racemic nicotine can't offer." 10

¹⁰ https://www.hkhangsen.com/show/index/cid/7/id/6.html



- 29. On November 18, 2020—after the publication of Zanoprima's United States patent application for the '962 Patent—Hangsen filed Chinese Patent Application No. 112409327A (the "'327 Application"). The '327 Application claims a process that utilizes imine reductase enzymes to convert myosmine into (S)-nornicotine, which then undergoes a reductive methylation reaction with formaldehyde or formaldehyde-based compounds to create (S)-nicotine. Upon information and belief, on or about June 17, 2021, the Chinese Patent Office rejected the '327 Application because it lacked novelty over the PCT application for Zanoprima's '962 Patent.
- 30. On information and belief, Hangsen manufactures the Accused Products, such as MOTiVO, in accordance with the methods described in the rejected '327 Application in a manner that infringes the '962 Patent.
- 31. On information and belief, Hangsen also provides, sells, and/or offers to sell MOTiVO-branded Accused Products to Genmist, a company that sells nicotine pouches throughout the world, including the United States. Genmist advertises on its website that Genmist nicotine pouches utilize "[t]he patented synthetic nicotine Motivo [that] has already been used on nicotine pouches and HNB products sold to worldwide."

¹¹ https://www.genmist.shop/blogs/genmist-blog/top-nicotine-pouch-brands

E. Hangsen's Knowledge of the Asserted Patents and Accused Products

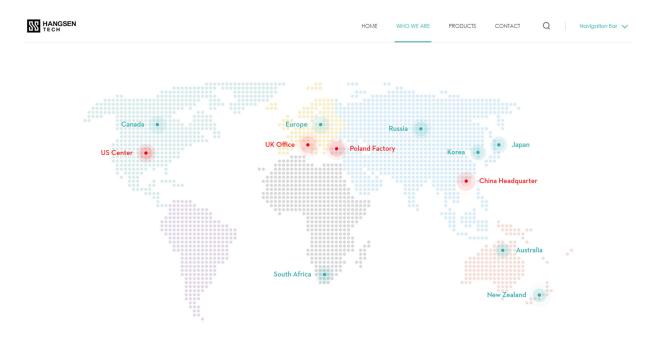
- 32. On December 20, 2021, counsel for Zanoprima sent a letter to Hangsen directors and legal counsel providing notice of the Asserted Patent ("Notice Letter"). Attached as Exhibit 3 is a true and correct copy of the Notice Letter, which is incorporated herein.
- 33. In the Notice Letter, Zanoprima notified Hangsen that the Accused Products infringe the '962 Patent.
- 34. Moreover, on information and belief, based on the rejection for the '327 Application that Hangsen received from the Chinese Patent Office on or about June 17, 2021, Hangsen was aware that the method described in the '327 Application was already described in the '962 Patent, and that any product produced by such method and imported, sold, or used in the United States would be infringing Zanoprima's '962 patent.

CLAIM

(Infringement of U.S. Patent No. 10,913,962)

- 35. Zanoprima re-alleges and incorporates herein by reference all previous factual allegations.
- 36. On information and belief, Hangsen has directly infringed and continues to infringe at least claim 1 of the '962 patent literally or under the doctrine of equivalents by importing into the United States, using, selling, and/or offering for sale in the United States, without authority or license, the Accused Products, in violation of at least 35 U.S.C. § 271(g).
- 37. On information and belief, Hangsen imports large quantities of the Accused Products for sale and distribution to customers located in the United States. In addition, Hangsen publicly admits that it operates a U.S.-based center that engages in the importation of Accused

Products into the United States as well as the distribution and/or sale of the Accused Products in the United States.¹²



- 38. On information and belief, Hangsen sells and/or offers for sale the Accused Products within the United States. On information and belief, employees of Hangsen knowingly engage in email correspondence with U.S. manufacturers, distributors, and customers to offer to sell and sell the Accused Products. On information and belief, this email correspondence includes specific prices per amount of Accused Product to be imported into the United States.
- 39. On information and belief, the Accused Products are manufactured by a process that practices every step of at least claim 1 of the '962 Patent. For example, upon information and belief, during the manufacture of the Accused Products, myosmine is reduced with an imine reductase enzyme to form (S)-nornicotine. Further, upon information and belief, the (S)-nornicotine is reductively methylated to (S)-nicotine using formaldehyde or a formaldehyde-based compound in the presence of a reductant. Upon information and belief, use of a formaldehyde or

¹² https://www.hkhangsen.com/list/index/cid/3.html

- a formaldehyde-based compound to reductively methylate the (S)-nornicotine is the only commercially-viable method to perform that step.
- 40. On information and belief, Hangsen's manufacture of the Accused Products utilizes an imine reductase enzyme to reduce myosmine to (S)-nornicotine. On information and belief, Hangsen utilizes an imine reductase enzyme to reduce myosmine to (S)-nornicotine in accordance with the processes described in its rejected '327 Application.
- 41. On information and belief, Hangsen's manufacture of the Accused Products uses formaldehyde or a formaldehyde-based compound in the presence of a reductant.
- 42. On information and belief, the Accused Products are neither materially changed by subsequent process nor become trivial and nonessential components of another product. To the contrary, the synthetic (S)-nicotine of the Accused Products is an essential component of final commercial products.
- 43. On information and belief, Hangsen has knowingly induced and continues to induce others, including its affiliates, suppliers, contract manufacturers, distributors, and customers to infringe one or more claims of the '962 Patent, including, but not limited to, claim 1, pursuant to 35 U.S.C. § 271(b), by actively encouraging and/or instructing others to import into the United States or make, use, sell, and/or offer to sell in the United States the Accused Products.
- 44. On information and belief, Hangsen sells or offers for sell the Accused Products to third parties that incorporate the Accused Products into third party products (the "Third Party Products"). On information and belief, Hangsen assists third parties, directly and/or through intermediaries, in the development of the Third Party Products and supports the sales of the Third Party Products.

- 45. On information and belief, Hangsen has had the specific intent, or has been willfully blind, to induce others to infringe the '962 Patent including inducing others to import, make, use, sell, and/or offer to sell, in the United States, the Third Party Products that include Accused Products, whose manufacture, use, sale, offer for sale, or importation in the United States constitute direct infringement of at least one claim of the '962 Patent. On information and belief, since at least the date of the Notice Letter, Hangsen has known that third parties who import, sell, offer to sell, or use the Accused Products in the United States are directly infringing the '962 Patent.
- 46. On information and belief, the Third Party Products are imported into the United States, or manufactured in the United States, for use, sale, and/or offer for sale in Texas and throughout the United States.
- 47. On information and belief, to the extent any entity other than Hangsen, including but not limited to any of Hangsen's partners, subsidiaries, parent companies, or agents, imports the Accused Products or the Third Party Products into the United States for or on behalf of Hangsen (the "Third Party Importer"), Hangsen is liable for inducement of infringement by the Third Party Importer. Hangsen has encouraged the Third Party Importer to infringe the '962 Patent and intended that it do so. This encouragement includes assisting, ordering or instructing the Third Party Importer to import the Accused Products and/or Third Party Products into the United States, providing directions and other materials to the Third Party Importer to enable such importation, and/or conditioning the receipt of benefits (including but not limited to payment) to the Third Party Importer on such importation. On information and belief, this behavior has continued at least since Hangsen first became aware of the '962 Patent and the infringement thereof.
- 48. On information and belief, Hangsen imports into the United States or sells or offers to sell within the United States materials and apparatuses that contribute to the direct infringement

of others within the United States, including its affiliates, suppliers, contract manufacturers, distributors, and customers. For example, the Accused Products constitute a material part of one or more claims of the '962 Patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, since at least the date of the Notice Letter, Hangsen has known that the Accused Products constitute a material part of the inventions of the '962 Patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Hangsen sells or offers to sell the Accused Products to third parties, such as affiliates, suppliers, contract manufacturers, distributors, and customers, who directly in infringe the '962 Patent by selling, offering for sell, using, making and/or importing without authority or license, Third Party Products that include the Accused Products.

- 49. Hangsen has benefitted and continues to benefit from the importation into the United States and the use, sale, or offer of sale in the United States of the Accused Products or the Third Party Products.
- 50. Zanoprima has suffered, and continues to suffer, damages as a result of Hangsen's infringement of the '962 Patent.
- 51. Hangsen has continued to infringe the '962 Patent since at least December 20, 2021, despite being on notice of the '962 Patent and its infringement. Hangsen has therefore infringed the '962 Patent knowingly, willfully, deliberately, and in disregard of Zanoprima's patent rights since at least December 20, 2021, at least by performing acts of infringement with actual knowledge of its direct and indirect infringement or while remaining willfully blind to the fact of its direct and indirect infringement. As a result of at least this conduct, Zanoprima is entitled to enhanced damages under 35 U.S.C. § 284 and to attorneys' fees and costs under 35 U.S.C. § 285.

52. Zanoprima reserves the right to modify its infringement theories as discovery progresses in this case. Zanoprima shall not be estopped or otherwise limited or restricted for the purposes of its infringement contentions or its claim constructions by allegations provided within this Complaint.

SUPPORT FOR PRELIMINARY AND PERMANENT INJUNCTION

- 53. Zanoprima incorporates by reference all previous factual allegations.
- 54. Immediate and irreparable harm has resulted, and will continue to result, from Hangsen's infringement of the '962 Patent.
- 55. Because Zanoprima's remedy at law is inadequate, Zanoprima seeks preliminary and permanent injunctive relief. Zanoprima is threatened with losing market share and competitive advantage, in amounts that may be impossible to determine, unless Hangsen is enjoined and restrained by Order of the Court.
- 56. The hardship of Hangsen's continued infringement of the '962 patent on Zanoprima, including the hardship of not being able to exclude others from practicing its patented invention, outweighs any potential hardship on Hangsen. As such, a remedy in equity is warranted.
- 57. Public policy supports granting preliminary and permanent injunctive relief to prevent further infringement of the '962 Patent.

PRAYER FOR RELIEF

WHEREFORE, Zanoprima prays for judgment against Defendant as follows:

- A. The Defendant has infringed and, unless enjoined, will continue to infringe the '962 Patent;
- B. The Defendant has willfully infringed the '962 Patent;

- C. That Defendant be enjoined from infringing the '962 Patent, or if its infringement is not enjoined, that Defendant be ordered to pay ongoing royalties to Zanoprima for any post-judgment infringement of the '962 Patent;
- D. The Defendant pay Zanoprima damages to compensate Zanoprima for Defendant's past infringement and any continuing or future infringement of the '962 Patent, together with interest and costs, under 35 U.S.C. § 284;
- E. That Defendant be ordered to pay prejudgment and post-judgment interest on the damages assessed;
- F. That Defendant pay Zanoprima enhanced damages pursuant to 35 U.S.C. § 284;
- G. That Defendant be ordered to pay supplemental damages to Zanoprima, including interest, with an accounting, as needed;
- H. That this is an exceptional case under 35 U.S.C. § 285, and that Defendants pay Zanoprima's attorneys' fees and costs in this action; and
- I. That Zanoprima be awarded such other and further relief, including equitable relief, as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Zanoprima hereby demands a trial by jury on all issues triable to a jury.

Dated: March 12, 2022 Respectfully submitted,

/s/ Marc B. Collier

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